UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

April 23, 2013

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 71847-6, Klorsept
DP Barcode: 408324

From: Marcus Rindal, Microbiologist
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Product Science Branch
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Thru: Emily Mitchell, Chief
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Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Medentech Ltd
Whitemill Industrial Estate, Clonard Road
Wexford, Ireland

Formulations from Label

Active Ingredient(s)	% by wt.
Sodium Dichloroisocyanurate.....	48.21%
Inert Ingredients.....	51.79%
Total	100.00%

I. BACKGROUND

The product, Klorsept (Reg. No. 71847-6), is an Agency registered disinfectant (bactericide, virucide, food contact sanitizer, cleaner) for use on pre-cleaned, hard, non-porous, inanimate surfaces in institutional, residential, healthcare, and commercial environments such as breweries, food processing plants, schools, hospitals, nursing homes, child care centers, daycare centers, restaurants, veterinary clinics, milk processing facilities, dairy farms, poultry premises, hatcheries, laboratories, and hospital or medical environments.

The applicant is submitting data to amend the registration to support a household disinfectant claim, effectiveness against Swine influenza virus H1N1, a general healthcare disinfectant claim, and effectiveness against *Clostridium difficile* spores. Studies were conducted by Microbiotest, located at 105 Carpenter Drive, Sterling, VA 20164 and ATS Labs, located at 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121.

The data package contains a letter from the applicant's representative to the Agency (dated October 10, 2012), an Application for Pesticide, Confidential Statement of Formula, Certification with Respect to Citation of Data, Data Matrix, amended label with changes and copies of proposed label, efficacy studies (MRID 490291-01 to 490291-04), and statements of no confidentiality for all 4 studies.

II. USE DIRECTIONS

The product is an effervescent tablet designed as a food contact sanitizer for kitchenware and food-contact surfaces of equipment. The product is also designed as a one-step disinfectant, virucide, fungicide, and sanitizer for non-food contact pre-cleaned, hard, non-porous, inanimate surfaces, including: floors, sinks, stoves, toilets, bathtubs, showers, bathroom fixtures, shelves, racks, carts, refrigerators, coolers, glazed tile, linoleum, vinyl, glazed porcelain, plastic, stainless steel, glass, and countertops in institutional, residential, healthcare, and commercial environments.

Directions on the proposed label provide the following information regarding preparation and use of the product for general disinfection: add 1 KLORSEPT tablet to 1 gallon of water (77°F/25°C) to obtain a concentration of 958 ppm (mg/Litre) of available chlorine. This solution must be freshly prepared. Clean surface then apply solution with mop, cloth, sponge, brush, foaming equipment, or coarse trigger sprayer. Allow surface to remain wet for 10 minutes. Wipe with a brush, sponge, or cloth and allow to air dry. Prepare a fresh solution daily or when solution becomes soiled or diluted. All treated equipment that will contact food, feed, or drinking water must be rinsed with potable water before reuse.

Directions on the proposed label provide the following information regarding preparation and use of the product for surfaces contaminated with *Clostridium difficile* spores: add 4 KLORSEPT tablets to 1 gallon of water (77°F/25°C) to obtain a concentration of 1917 ppm (mg/Litre) of available chlorine. Clean surface then apply solution with mop, cloth, sponge, brush, foaming equipment, or coarse trigger sprayer. Allow surface to remain wet for 10 minutes. Wipe with a brush, sponge, or cloth and allow to air dry. Prepare a fresh solution daily or when solution becomes soiled or diluted. All treated equipment that will contact food, feed, or drinking water must be rinsed with potable water before reuse.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Sporicidal Disinfectant against *Clostridium difficile*: The Agency has established interim guidance for the efficacy evaluation of antimicrobial products (e.g., dilutable products, ready-to-use products, spray products, towelettes) that are labeled for use to treat hard, non-porous surfaces in healthcare settings contaminated with spores of *Clostridium difficile*. The effectiveness of such a product must be substantiated by data derived from one of the following four test methods: Most recent version (2006) of AOAC Method 966.04: AOAC Sporicidal Activity of Disinfectants Test, Method I for *Clostridium sporogenes*; AOAC Method 2008.05: Quantitative Three Step Method (Efficacy of Liquid Sporicides Against Spores of *Bacillus subtilis* on a Hard Nonporous Surface); ASTM E 2414-05: Standard Test Method for Quantitative Sporicidal Three Step Method (TSM) to Determine Efficacy of Liquids, Liquid Sprays, and Vapor or Gases on Contaminated Carrier Surfaces; or ASTM E 2197-02: Standard Quantitative Carrier Test Method to Evaluate the Bactericidal, Fungicidal, Mycobactericidal, and Sporicidal Potencies of Liquid Chemical Germicides. Modifications to each test method will be necessary to specifically accommodate spores of *Clostridium difficile*. Because *Clostridium difficile* is an obligate anaerobe, testing should ensure adequate incubation conditions for the recovery of viable spores. The following toxigenic strains of *Clostridium difficile* may be used for testing: ATCC 700792, ATCC 43598, or ATCC 43599. All products must carry a pre-cleaning step, thus no organic soil should be added to the spore inoculum. Results must show a minimum 6 log reduction of viable spores in 10 minutes or less. Control carrier counts must be greater than 10^6 spores/carrier.

Broad/General Spectrum Disinfectants for Use on Hard Non-Porous Surfaces: The effectiveness of broad spectrum disinfectants (represented in labeling as having efficacy against both Gram-negative and Gram-positive bacteria) for use on hard surfaces must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products). Sixty carriers must be tested with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old, against both *Salmonella enterica* (formerly known as *Salmonella choleraesuis*) (ATCC 10708) and *Staphylococcus aureus* (ATCC 6538). To support products labeled as "disinfectants," killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level. If the product is intended to be represented as bactericidal in the presence of organic soil (one-step), an appropriate organic soil, such as 5 percent blood serum, should be included with the bacterial inoculum. For the AOAC International Use-Dilution Methods, the Germicidal Spray Products as Disinfectants test, and single-use towelettes, the product should kill the test microorganisms on 59 out of each set of 60 carriers/slides in ≤ten minutes. In addition, per the 2009 AOAC revisions for the Use-Dilution Method, the mean log density for *S. aureus* is to be at least 6.0 (corresponding to a geometric mean density of 1.0×10^6); a mean log density <6.0 invalidates the test. The mean log density for *Salmonella enterica* is to be at least 4.0 (corresponding to a geometric mean density of 1.0×10^4); a mean log density <4.0 invalidates the test.

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments: The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products). Sixty carriers must be tested with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old, against *Salmonella enterica* (ATCC 10708; formerly *Salmonella choleraesuis*), *Staphylococcus aureus* (ATCC 6538), and *Pseudomonas aeruginosa* (ATCC 15442). To support products labeled as "disinfectants," killing

on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level.

Virucides: The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

IV. SUMMARY OF SUBMITTED STUDIES

1. **MRID 490291-01 "Standard Quantitative Disk Carrier Test Method" against *Clostridium difficile* – spore form (ATCC 43598) for KLORSEPT, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – September 17, 2012. Project Number A13936.**

This study was conducted against *Clostridium difficile* – spore form (ATCC 43598). Three lots (Lot Nos. C233, C495, and C638) of the product, KLORSEPT, were tested using the ASTM E 2197-02: Standard Quantitative Carrier Test Method to Evaluate the Bactericidal, Fungicidal, Mycobactericidal, and Sporicidal Potencies of Liquid Chemical Germicides as described in protocol number MED87080212.QDCT. Lot No. C233 was ≥60 days old at the time of testing. Brushed stainless steel disk carriers (diameter =1 cm, thickness =0.7 mm) were used in the test. New stainless steel disk carriers were soaked in a 1-5% solution of Triton X-100 for 2-4 hours. Carriers were then thoroughly rinsed at least 4 times in deionized water or until all soapy residue was gone. All disks were checked for pitting, rust or other defects prior to sterilization. All disks with defects were discarded. Cleaned carriers were placed into a sterile vessel and autoclave sterilized. An equivalent dilution of 20g/3 L (defined as 4 tablets of test substance + ~3 L of sterile tap water) was prepared. For Lot C233 (>60 days old), a defined dilution of 4 tablets + 3170 mL of diluent was prepared by adding one (1) tablet of test substance + 792.5 mL of sterile tap water. For Lot C495, a defined dilution of 4 tablets + 3260 mL of diluent was prepared by adding one (1) tablet of test substance + 815.0 mL of sterile tap water. For Lot C638, a defined dilution of 4 tablets + 3250 mL of diluent was prepared by adding one (1) tablet of test substance + 812.5 mL of sterile tap water. The prepared test substance was homogenous as determined by visual observation and was used within three hours of preparation. From a stock source, five 10 mL tubes of BHI broth were inoculated with the test organism. The broth tubes were incubated for 2 days at 35-37°C under anaerobic conditions. Following incubation, the broth culture was vortex-mixed and 80 CDC Anaerobic Blood agar plates were inoculated with 500 µL of broth culture per plate. The inoculum was spread over the plates and the plates were incubated for 7 days at 35-37°C under anaerobic conditions. Following incubation, the growth was harvested from the plates by adding 3.0 mL of sterile deionized water to each plate and gently scraping each plate with a sterile cell scraper. The

liquid was removed from each plate and transferred to a sterile 50 mL conical tube. The suspension was centrifuge-concentrated at 3700 RPM for 20 minutes and the pellet was concentrated in 25.0 mL of sterile deionized water. The suspension was centrifuge-concentrated a second time at 3700 RPM for 10 minutes. The supernatant was removed and the pellet was resuspended in sterile deionized water (approximately equivalent to the volume of supernatant removed). The suspension was centrifuge-concentrated a third time at 3700 RPM for 10 minutes. The supernatant was removed and the pellet was resuspended in sterile deionized water (approximately equivalent to the volume of supernatant removed). The culture was macerated to uniformity and was stored at 2-8°C for four months prior to use. The spore suspension was evaluated for spore purity by Malachite green stain and microscopic analysis and demonstrated a 92% spore to vegetative cell ratio. Up to 20 sterile stainless steel disks were transferred to individual sterile Petri dishes matted with filter paper. Ten (10) µL of culture was placed in the center of each disk using a calibrated positive displacement pipettor and the inoculum was not spread. After all disks in the Petri dish were inoculated, the cover was replaced. The contaminated carriers were placed in a desiccator containing active desiccant. A vacuum was drawn and the carriers were dried for 5 hours 17 minutes under ambient conditions. At the end of the drying period, the carriers were examined to assure the inoculum had not run off the carrier. Any carriers showing signs of run-off were discarded. Each contaminated and dried carrier was placed into a separate sterile 15 mL flatbottom Teflon QCT vial with the contaminated side facing up. Fifty (50) µL of the test substance at its use-dilution was applied to the center of the disk using a positive displacement pipettor. Care was taken to ensure that the entire inoculated area on the disk was covered with test substance. The test substance was allowed to remain in contact with the disk for 10 minutes at room temperature (20°C) and 52% relative humidity. Following the 10 minute exposure time, 10.0 mL of neutralizer was added to the vial containing the carrier. The surface of the carrier was scraped with a sterile loop to elute any visible inoculum. The vial containing the carrier was vortex mixed for approximately 45-60 seconds. This represents the 10° dilution. Individual sterile filter units with 0.45 µm porosity were pre-wetted with approximately 10.0 mL of sterile saline. The 10° dilution was filtered in its entirety by transferring the liquid from each vial onto the surface of a filter membrane. Approximately 10.0 mL of sterile saline was added to the vial containing the carrier and the vial was vortex mixed. The rinse solution was filtered using the same filter membrane as the 10° dilution. This rinse step was repeated three times for a total of four rinses. The filter was rinsed with approximately 40.0 mL of sterile saline. The contents were evacuated. Each filter membrane will be removed aseptically from the filter unit and placed onto the surface of an agar plate appropriate for the recovery of *C. difficile* spores. The subcultures were incubated anaerobically for 48±4 hours at 35-37°C. Following incubation, the number of survivors was enumerated. Representative subcultures showing growth were stained and/or biochemically assayed to confirm or rule out the presence of the test organism. Study controls included Purity Control, Carrier Sterility Control, Neutralizer Sterility Control, Initial Suspension Population Control, Neutralization Confirmation Control, Carrier Population Control, and HCl Resistance.

2. **MRID 490291-02 "AOAC Use Dilution Test Broad Spectrum," against *Staphylococcus aureus* (ATCC 6538) and *Salmonella enterica* (ATCC 10708)" for KLORSEPT, by Kathryn Dormstetter. Study conducted at Microbiotest Labs. Study completion date – July 6, 2011. Project Identification Number 642-117.**

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Salmonella enterica* (ATCC 10708). Three lots (Lot No. B798, B799, and B679 – aged at least 60 days) of the product, KLORSEPT, effervescent disinfectant tablets, were tested with a modification of

the Use Dilution Method, Official Methods of Analysis, Sixteenth edition, 2006, AOAC as described in Protocol Identification Number 642.1.06.20.11.
All three lots were prepared using 400 ppm AOAC Hard Water (±2.9%) as the diluent.

Lot No. 1: B799	Dilution: One tablet plus 4,163.5 mL (1.1 gallon) diluent
Lot No. 2: B798	Dilution: One tablet plus 3,785 mL (one gallon) diluent
Lot No. 3: B679*	Dilution: One tablet plus 3,785 mL (one gallon).diluent (*aged at least 60 days)

Sixty replicates, per microorganism were evaluated per each of the three lots of the product (one of which was at least 60 days old). *Staphylococcus aureus* and *Salmonella enterica* cultures were dried on stainless steel penicylinders and exposed to the test agent at room temperature and for a ten minute contact time. The carriers were removed from the test agent, neutralized and cultured. Carriers were inoculated for 15 minutes (20 carriers per 20 mL inocula) and dried for 30 minutes. Tubes containing the test agent were maintained at the testing temperature throughout the test. One contaminated carrier was added to each tube; the tube swirled to mix; and the carrier allowed to remain in contact with the test agent for 10 minutes. After the contact time, the carriers were removed, transferred to recovery broth/neutralizer, Letheen Broth containing 0.2% Sodium Thiosulfate, and the tubes were thoroughly shaken. All tubes were incubated at 37±2°C for 48±2 hours and the results recorded as visible growth or no visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

3. **MRID 490291-03 "AOAC Use Dilution Test – *Pseudomonas aeruginosa* (ATCC 15442)" for KLORSEPT, by Emily Winokurzew. Study conducted at Microbiotest. Study completion date – August 29, 2012. Laboratory Project Identification Number 642-120.**

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). Three lots (Lot No. C233, C495, and C638) of the product, KLORSEPT, effervescent disinfectant tablets, were tested with the Use Dilution Method, based on the Official Methods of Analysis, Sixteenth edition, 1995, AOAC; as required by EPA Product Performance Guidelines (OCSPP 810.2000 and 810.2200). The study is described in Protocol Identification Number 642.1.08.02.12. All three lots were prepared using 400 ppm AOAC Hard Water (±2.9%) as the diluent.

Lot No. 1: C233	Dilution: 1 tablet + 3170 mL diluent
Lot No. 2: C495	Dilution: 1 tablet + 3260 mL diluent
Lot No. 3: C638	Dilution: 1 tablet + 3250 mL diluent

Sixty replicates were evaluated per each of the three lots of the product (Lot No. C233 was at least 60 days old). A *Pseudomonas aeruginosa* culture was dried on stainless steel penicylinders and exposed to the test agent at room temperature for a ten minute contact time. The carriers were removed from the test agent, neutralized and cultured. Carriers were inoculated for 15 minutes (20 carriers per 20 mL inocula) and dried for 40 minutes at 38-42% RH. Tubes containing the test agent were maintained at the testing temperature throughout the test. One contaminated carrier was added to each tube; the tube swirled to mix; and the carrier allowed to remain in contact with the test agent for 10 minutes. After the contact time, the carriers were removed, transferred to the recovery broth/neutralizer, Letheen Broth containing 0.2% Sodium Thiosulfate, and the tubes were thoroughly shaken. All tubes were incubated at 36±1°C for 48±2 hours and the results recorded as visible growth or no visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

4. **MRID 490291-04 "Virucidal Efficacy Test Using Swine Influenza Virus (H1N1)," for KLORSEPT, by Zheng Chen. Study conducted at Microbiotest. Study completion date – September 15, 2009. Laboratory Project Identification Number 642-112.**

This study was conducted against Swine Influenza Virus (H1N1), A/ Swine/ 1976/ 31, ATCC VR-99), using MDCK cells (ATCC CC-34) as the host system. Two lots (Lot Nos. 09HA149 and 07F7482) of the product, KLORSEPT (called 2.5 gm NaDCC Tablets in the study), were tested using the procedure outlined in the American Society for Test Materials (ASTM) test method designated E1053-97, according to Microbiotest Labs Protocol No. 642.1.08.19.09. The effervescent tablet product was received ready-to-use. One tablet was dissolved in 10 liters of sterile deionized water. The stock virus culture was adjusted to contain 5% serum as the organic soil load. For each lot of the test agent, an aliquot of 0.4 mL of stock virus was spread over an area of approximately 4 in^2 that was marked on the underside of presterilized glass Petri dishes. Then the virus was allowed to dry at ambient temperature for 30 minutes. One carrier was prepared for each replicate of test agent from each lot. Another carrier was prepared for the plate recovery control. Additionally, one carrier was prepared for the neutralizer effectiveness/viral interference control using cell culture medium (CCM) in lieu of virus. For each lot of product, separate dried virus films were exposed to 2.0 mL of the product for 10 minutes at 20°C. Two lots of the test agent were tested at the 10 minute contact time. One replicate was tested for each lot of the test agent. For each replicate run, after the inoculum has dried, 2.0 mL of the test agent was added, assuring that the dried virus film was completely covered. The plates remained at the temperature and for the 10 minute contact period. After the contact period, the test agent was neutralized with 2.0 mL of neutralizer, Minimum Essential Medium (MEM) + 0.01mol/L $Na_2S_2O_3$ + 1% Fetal bovine serum, and the mixture was scraped from the surface of the dish with a cell scraper. This was considered approximately a 10^{-1} dilution. The residual infectious virus in both test and controls were detected by viral-induced cytopathic effect (CPE). Selected dilutions of the neutralized inoculum/disinfectant mixture were added to cultured host cells (at least four wells per dilution, per reaction mixture) and incubated at 36±2C with 5±1% CO2 for a period of 4-6 days. The cell plates were washed with phosphate buffered saline (PBS) twice before inoculation. The host cell cultures were observed and fed as necessary, during the incubation period. The host cells were examined microscopically for presence of infectious virions upon completion of incubation. The resulting virus-specific CPE and test agent-specific cytotoxic effects were scored by examining both test and controls. These observations were recorded. Controls included those for dried virus count/ plate recovery control, cytotoxicity, and neutralization (both product lots). Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

V. RESULTS

Table 1. Virucidal Test Results for KLORSEPT MRID 490291-01

Results Summary for Standard Quantitative Disk Carrier Test Method				
Test Organism	Lot No.	Average # Survivors/ Test Carrier (Average Log_{10} of Test Carriers)	Average # Survivors/ Control Carrier (Average Log_{10} of Control Carriers)	Percent Reduction (Log_{10} Reduction)
Clostridium difficile - spore form (ATCC 43598)	C233	<1.74 (<0.24)	4.37×10^5 (6.64)	>99.9999% (>6.40)
	C495	<1.00 (<0.00)	4.37×10^5 (6.64)	>99.9999% (>6.64)
	C638	<1.66 (<0.22)	4.37×10^5 (6.64)	>99.9999% (>6.64)
CARRIER POPULATION CONTROL RESULTS: Geometric Mean (CPU/carrier)				4.37×10^5

A value of <1 was used in place of zero for calculation purposes.

Table 2. Broad/General Disinfection Test Results for KLORSEPT

Results Summary for AOAC Use Dilution Test Method				
MRID Number	Sample Batch Reference Number	Organism		Average Carrier Population (CFU/ carrier)
		S. aureus	*S. enterica*	
490291-02	B799	0/60	0/60	*S.a.* 4.1×10^6 *S.e.* 2.0×10^6
	B798	1/60	0/60	
	B679	0/60	1/60	

Table 3. Hospital Disinfection Test Results for KLORSEPT *P. aeruginosa* ONLY

Results Summary for AOAC Use Dilution Test Method			
MRID Number	Sample Batch Reference Number	Organism	Average Carrier Population (CFU/ carrier)
		P. aeruginosa	
490291-03	C233	1/60	5.9×10^6
	C495	1/60	7.1×10^6
	C638	1/60	7.6×10^6

Table 4. Virucidal Test Results for KLORSEPT

Results Summary for Virucidal Efficacy Test Method				
MRID Number	Organism	Dilution*	Results per Lot	
			09HA149	07F7482
490291-04	Swine Influenza (H1N1) Virus	10^{-2} to 10^{-7}	Complete inactivation	Complete inactivation
		Titer (Log_{10} $TCID_{50}$/mL)	≤1.50	≤1.50
		Load (Log_{10} $TCID_{50}$) per carrier (0.4mL challenge)	≤1.10	≤1.10
		Log_{10} Reduction	≥5.00	≥5.00

* Dilution refers to fold of dilution from virus inoculum.

VI. CONCLUSIONS

1. The submitted efficacy data (MRID 490291-01) **support** the use of a **1917 ppm** solution of the product, KLORSEPT, as a disinfectant against spores of *Clostridium difficile* on pre-cleaned, hard, non-porous surfaces diluted in sterile tap water for a 10-minute contact time (see Table 1.). A >6-log reduction in viable spores was reported by the laboratory. At least one of the product lots tested was at least 60 days old at the time of testing. Carrier counts met the acceptance criterion of $>10^6$ spores/carrier. Neutralizer efficacy verification testing demonstrated that the neutralizer was effective in neutralizing the antimicrobial activity of the product. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth. Test spores showed resistance to acid for >10 minutes.

2. The submitted efficacy data (MRID 490291-02) **support** the use of a **958 ppm** solution of the product, KLORSEPT, as a general or broad spectrum disinfectant with bactericidal activity (see Table 2.) against *Staphylococcus aureus* and *Salmonella enterica*, on hard, non-porous surfaces with a contact time of 10 minutes at 21°C prepared using 400 ppm AOAC Hard Water (±2.9%) as the diluent. The necessary killing was observed in the subcultures (59 or 60 out of 60) of the required number of carriers tested against the required number of product lots. One of the product lots tested was at least 60 days old at the time of testing. Neutralization confirmation testing showed positive growth of the microorganisms. Purity controls were reported as pure. Viability controls were positive for growth. Sterility controls did not show growth.

3. The submitted efficacy data **support** the use of a **958 ppm** solution the product, KLORSEPT, as a disinfectant with bactericidal activity against *Staphylococcus aureus* (MRID 490291-02, see Table 2.) and *Pseudomonas aeruginosa* (MRID 490291-03, see Table 3.) on hard, non-porous surfaces for a 10-minute contact time at 20-21°C prepared using 400 ppm AOAC Hard Water (±2.9%) as the diluent. The necessary killing was observed in the subcultures (59 or 60 out of 60) of the required number of carriers tested against the required number of product lots. At least one of the product lots tested for each organism was at least 60 days old at the time of testing. Neutralization confirmation testing showed positive growth of the microorganism. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

4. The submitted efficacy data **support** the use of a **958 ppm** solution the product, KLORSEPT, as a one-step disinfectant with virucidal activity against Swine Influenza (H1N1) Virus (MRID 490291-04, see Table 4.) on hard, non-porous surfaces for a 10-minute contact time in the presence of 5% organic serum at 20-21°C prepared using sterile deionized water as the diluent. Cytotoxicity was not observed in either batch at any dilution tested (≤ 0.50 $\log_{10}$). A recoverable virus titer of at least 10^4 was achieved. Complete inactivation (no growth) was indicated in all higher dilutions tested. The neutralization control (non-virucidal level of the test substance) indicates that both batches of the test substance were neutralized at ≤ 0.50 $\log_{10}$.

VII. RECOMMENDATIONS

1. The proposed label claims that the product, KLORSEPT, is an effective disinfectant against spores of *Clostridium difficile* on pre-cleaned, hard, non-porous surfaces for 10-

minute contact time, are acceptable as they are supported by the submitted data.

2. The proposed label claims are acceptable regarding the use of the product, KLORSEPT, as a general or broad spectrum disinfectant against *Staphylococcus aureus* (ATCC 6538) and *Salmonella enterica* (ATCC 10708) for a 10 minute contact time at 21°C.

3. The proposed label claims are acceptable regarding the use of the product, KLORSEPT, as a disinfectant with bactericidal activity against *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442) for a 10 minute contact time at 21°C.

4. The proposed label claims are acceptable regarding the use of the product, KLORSEPT, as a disinfectant with Virucidal activity against Swine Influenza Virus (H1N1) for a 10 minute contact time at 20°C in the presence of organic soil (5% serum). The claim is acceptable and supported by the submitted data.